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To: House Subcommittee on Criminal Justice, Drug Policy and Human Resources

Date: November 1, 2005 Subject: Counterfeit Drugs

My name is Kevin Fagan, and while I am pleased to be invited to speak here today, I do so only because my son Tim was injured by counterfeit drugs. I would have preferred to have never heard of this subject.

Tim was 16 when he had an emergency liver transplant in 2002 in New York. He had a diseased liver, the cause of which was never determined. He was exceedingly fortunate to survive the disease and the surgery.

After being discharged home, he was given a medication called Epogen. This was designed to fight his anemia, a by-product of his medical condition. This is a very expensive drug, which he was injected with once a week.

Unfortunately, the drug that we thought he was receiving, and that my wife was personally injecting into him, was not the drug that was marked on the label. Hours after each injection, he would wake up in the night screaming in pain – as if someone had broken into the house and was attacking him. His entire body was racked in a cramp, which was not only excruciatingly painful, but terrified both Tim and the rest of the family as we did not know what, if anything was happening to his new liver.

Tim went through this each week for two months.

We finally learned from our local pharmacy -- one of the largest pharmacy chains in the country -- that there was counterfeit Epogen in the marketplace. Someone had apparently bought massive quantities of low dose Epogen at 2,000 u/ml and then re-labeled it as high dose Epogen at 40,000 u/ml. The low dose Epogen cost about \$22. The high dose Epogen cost about \$450. After the labels had been criminally changed, the vials were then re-sold into the secondary market. This delicate medication, which must be constantly refrigerated and never shaken, was then bought and sold by companies that simply turned a blind eye, not only to its origins, but also to the ways in which it had been handled and stored. They did this for one reason only. Greater profits. There was little concern about the criminal justice system, since the penalties are so light.

For two months my son was injected with a product that had been bought and sold about a dozen times. Our pharmacy bought the product from drug wholesaler AmerisourceBergen, which I have since learned is one of the largest companies in America, standing now at #22 on the Fortune 500 list with almost \$50B in revenues. Rather than buy the drugs from the manufacturer, AmerisourceBergen turned to the secondary market to fatten their profit margins.

When they bought the drugs, they did not know who all the prior owners were, or the conditions under which it had been stored. To this date, AmerisourceBergen has never paid a price before any governmental entity of any kind for its careless and reckless conduct in buying mystery medicine and peddling it as bona fide.

It is clear that our pharmaceutical supply system has holes in it, and that the holes are exploited by those who care more for profit than for safety.

One way to put a stop to this is with lawsuits and punitive damages, which we are currently pursuing. But such suits are difficult since the evidence is destroyed at the time it is injected or ingested, and proving an injury is difficult since the patients are already sick. Further, the fact that the industry does not track drugs by lot number -- as is done in many other industries -- makes it even more difficult to determine the prior owners of a particular lot of medication. The vast, vast majority of victims have no idea they were even victimized, with their doctors no doubt chalking up the ineffectiveness of the drug to the underlying disease.

I am therefore hopeful that you will assist us by supporting Tim Fagan's Law that is currently pending in Congress. This law will give far tougher penalties for counterfeiters and give the FDA far more investigative and enforcement capabilities.

On behalf of my son I thank you for the opportunity to come here and be heard.

For more information on counterfeit drugs:

Food and Drug Administration: http://www.fda.gov/counterfeit/

Rep. Steve Israel:

http://www.house.gov/israel/issues/counterfeitdrugs.htm

Turkewitz Law Firm Counterfeit Drug Resource Page: http://www.ericturkewitz.com/counterfeit-drugs.htm

Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply: http://www.dangerousdoses.com/

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